

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

SHARON SWANSON, Individually and	:	
as parent and natural guardian of	:	Case No. 2:14-cv-1052
D.S., a minor,	:	
	:	Judge George C. Smith
PLAINTIFFS,	:	
	:	Magistrate Judge Mark A. Abel
v.	:	
	:	
ABBOTT LABORATORIES	:	
	:	
and	:	
	:	
ABBVIE INC.	:	
	:	
DEFENDANTS.	:	

PROTECTIVE ORDER

WHEREAS, the discovery phase of this case will involve the exchange of confidential business information and information involving the privacy rights of individuals, including the parties;

WHEREAS, the Court wishes to expedite the free flow of information between the parties, facilitate the prompt resolution of disputes over confidentiality, protect the parties from undue burden and expense, and ensure that protection is afforded only to material so entitled, IT IS ORDERED as follows:

1. This Protective Order ("Order") governs the use and dissemination of all information, documents, or materials produced in the above-captioned case that are designated Confidential during discovery.

2. The parties to this Action shall not disclose documents, interrogatory answers, responses to requests for admission, testimony, or other information or materials properly designated confidential pursuant to this Order (“Confidential Information”) to any person (including representatives and employees of the producing or receiving party) except as provided herein.

3. “Confidential Information,” as used in this Order, is defined in accordance with Sixth Circuit law. Confidential Information includes any writing or communication reproducing, paraphrasing, or otherwise disclosing such information. Subject to the foregoing, Confidential information may include the following information:

- a. information that is not in the public domain and contains employee information, financial data and information, and any other information that may reasonably be characterized by a party as intellectual property, a trade secret, or confidential and proprietary information, including information protected from disclosure by FDA regulations including 21 C.F.R. § 20.63 and 21 C.F.R. § 314.430,;
- b. information provided to Abbott by third parties with the expectation that Abbott would keep such information confidential or pursuant to contracts that expressly require Abbott to maintain the confidentiality of the information of patients in clinical studies or adverse event reports as well as the physicians who reported to Abbott adverse events concerning one of their patients;
- c. information that is not generally available to the public that relates to, reflects or was or is used to help form Abbott’s research, business and legal strategies, such as business marketing plans or studies;
- d. confidential client lists;
- e. sales data that Abbott keep’s confidential;
- f. pricing and financial information;
- g. discount information;
- h. rebate information;
- i. plaintiffs’ confidential personal and financial information, including but not limited to: medical records, insurance records, social security numbers, drivers’ license numbers, and banking information;
- j. non-public financial data that would reveal Abbott’s future strategic commitments;
- k. information relating to job performance evaluations or disciplinary actions; and

- I. information that is not generally available to the public that relates to consumer purchasing habits, pricing information, sales techniques, sales volumes.

For purposes of this Order, "Trade Secret" includes any formula, compilation, program, plan, device, design, method, technique, process or other information used in the producing party's business and for which confidentiality or sensitivity has been reasonably maintained. "Proprietary Information" means any information in which a party has a protectable interest, which may include a party's finances, processes, products, services, research and development, sales and marketing, strategies and technologies, trade secret or other confidential research, development or commercial information or other non-public information about the financial and business affairs of the parties.

4. The order governs any summary, compilation, notes, copy, electronic image or database containing Confidential Information to the same extent as the materials or information from which such summary, compilation, notes, copy, electronic image or database is made or derived.

5. A "Producing Party" is a party to this Action or any third party who produces or supplies information, documents, or other materials used in the Action. A Producing Party may designate as "Confidential" any information, document, or material that it reasonably and in good faith believes constitutes or contains Confidential Information. The Court deems "Confidential" all medical, billing, pharmacy, insurance, financial, and employment records of any Plaintiff or the relative of any Plaintiff.

6. The party designating material as "Confidential" ("Designating Party") shall clearly stamp the materials as "Confidential."

7. The parties shall initially consider all deposition testimony and exhibits in this Action to be "Confidential." The court reporter shall mark all deposition transcript pages with the designation "Confidential – Subject to Further Confidentiality Review."

8. To maintain the "Confidential" status of deposition testimony and exhibits, within 30 days of receipt of the final transcript, the Designating Party must notify all parties and the court reporter in writing of the specific pages and lines of the transcript that should be treated as Confidential. Only exhibits and portions of the transcript that were designated within that 30 day period may be deemed Confidential. Counsel for the party receiving the designations ("Receiving Party") may have immediate access to the deposition transcript, but prior to the page and line designations, the Receiving Party shall treat the entire transcript as Confidential.

9. The Receiving Party may only use Confidential Information for the following purposes:

- a. in connection with the Action,
- b. any other proceeding filed by one or more of the lawyers for Plaintiffs in the Action alleging birth defect injuries resulting from exposure to the product(s) at issue in this Action, or
- c. any other proceeding alleging birth defect injuries resulting from exposure to the product(s) at issue in this Action that has coordinated or cross-noticed discovery with this Action.

Notwithstanding the above limitations, Abbott may use Confidential Information for the purpose of reporting it to regulatory agencies in compliance with its obligations under federal law.

10. Confidential Information produced in this litigation may be disclosed only to:

- a. parties to this Action, including designated in-house counsel for Abbott (and the clerical, secretarial and other staff working for in-house counsel in the legal department) and any employee that Abbott deems necessary to disclose such information for the purpose of assisting in, or consulting with respect to, the preparation of this Action;
- b. counsel for the parties to this Action, including the partners, associates, and stenographic, secretarial, paralegal, clerical and other employees of such counsel;
- c. experts or consultants retained or consulted by the parties to this Action, including the partners, associates, and stenographic, secretarial, paralegal, clerical and other employees of such expert or consultant;
- d. any person who prepared or originated the document, who is indicated on its face as a recipient, or who otherwise legitimately received a copy, including but not limited to, any treating physician or healthcare provider of any Plaintiff, ("Treating Provider") whose medical or treatment records include the document;

- e. any Treating Provider, provided that: (1) the Confidential Information is not placed in the Treating Provider's possession, control, or in any files maintained by or on behalf of the Treating Provider, (2) such Confidential Information must be relevant to that Treating Provider's testimony or knowledge; and (3) Abbott may only show a Treating Provider medical records for the Plaintiff(s) that the Treating Provider treated;
 - f. any witness scheduled for a deposition, hearing, or trial in this Action where the Confidential Information is reasonably anticipated to relate to the testimony or knowledge of such witness;
 - g. the Court and related officials involved in this litigation, including judges, magistrates, commissioners, mediators, referees, jurors, court reports, videographers, and other Court personnel; and
 - h. any person the Court designates in the interest of justice, upon such terms the Court deems proper.
11. Prior to disclosing Confidential Information to any person listed in Paragraph 10(c), (e), or (h) above, the Receiving Party shall:
- a. provide such person with a copy of this Protective Order; and
 - b. obtain from the recipient a signed statement in the form attached as Exhibit A. The Receiving Party shall retain the signed statement. Unless the Court requires, the Receiving Party need not file the signed statement with the Court nor serve it upon opposing counsel. Parties are required to maintain copies of all signed statements they obtain and may be required to produce them *in camera* to the Court upon request.
12. When a party discloses Confidential Information to a Treating Provider pursuant to Paragraph 10(e), the opposing parties must be provided with copies or Bates numbers of the disclosed Confidential Information, unless the information is that described in Paragraph 10(d). Such Confidential Information must be disclosed at least three business days before any deposition of that Treating Provider. If a party first shows Confidential Information to a Treating Provider less than three business days before that Treating Provider's deposition, copies of any such Confidential Information must be produced to the opposing party before the start of the deposition.
13. When a party discloses Confidential Information to any person listed in Paragraph 10(a), (b), (d), or (f), the disclosing party shall:

- a. advise the recipient of this Order;
- b. direct the recipient to use the Confidential Information only for purposes: (1) in connection with this Action, or (2) in any other proceeding filed by one or more of the lawyers for Plaintiffs alleging birth defect injuries resulting from exposure to the product(s) at issue in this Action; and
- c. direct the recipient to refrain from disclosing such Confidential Information with any person other than those already subject to the terms of this Order.

14. A party's designation of information or material as Confidential is not determinative of whether the information is entitled to be deemed as Confidential Information. The parties shall be mindful that the Sixth Circuit values maintaining public access to court proceedings. *P&G v. Bankers Trust Co.*, 78 F.3d 219, 227 (6th Cir. 1996) quoting *Brown & Williamson Tobacco Corp. v. FTC*, 710 F.2d 1165, 1177 (6th Cir. 1983).

15. The parties must file a motion pursuant to Rule 79.3 of the Southern District of Ohio Civil Rules when filing documents under seal.

When the Receiving Party files materials designated Confidential (e.g. a motion, memorandum, etc. that contains or attaches Confidential Information), the Receiving Party shall file the materials conditionally under seal and provide the Designating Party contemporaneous notice that the materials have been filed under seal. If the Designating Party wishes the materials to remain filed under seal, the Designating Party must file a motion within 14 days and show good cause to justify court-imposed secrecy in accordance with Sixth Circuit precedent. *P&G v. Bankers Trust Co.*, 78 F.3d at 227. If the Designating Party fails to file such motion within 14 days, then the materials are unsealed. Similarly, when the Designating Party files its own materials under seal, it shall do so conditionally and shall contemporaneously file a motion to show good cause as to why the materials should remain under seal. If the Court grants the motion to seal, the materials remain filed under seal. If the Court denies the motion, the materials are unsealed.

16. This Order does not affect the admissibility of any document, testimony, or other evidence at trial.

17. A Designating Party may consent to the removal of a Confidential designation of documents or materials it produced by the Receiving Party in writing.

18. Any party may object to a Confidential designation as follows:

- a. the objecting party shall notify the Designating Party in writing of that objection;
- b. the objecting party shall specify the designated materials, or category or sub-set of information, to which the objection is made;
- c. the parties shall confer in good faith concerning any such objection;
- d. if the objection is not resolved within 10 days after mailing the notice, then the objecting party may file a motion to remove the designation of Confidential. If the objecting party files a motion, the parties shall continue to treat the information subject to dispute treated consistently with its designation.
- e. the Designating Party bears the burden of evidentiary proof to establish grounds for confidentiality in accordance with Sixth Circuit law and this Order as to each document or sub-set of documents where the Confidential designation has been placed at issue.
- f. If the parties brief their motions, they shall file the briefing under seal.

19. Neither the taking of any action in accordance with the provisions of this Order, nor the failure to object thereto constitutes a waiver of any claim or defense in this Action.

20. In the event a party discovers that it inadvertently produced materials containing Confidential Information without designating them as Confidential in accordance with this Protective Order, that party may, in good faith, provide written notice to the Receiving Party that the materials should be treated as Confidential in accordance with this Order. Upon receipt of such notice, the Receiving Party shall treat such materials as Confidential Information. Upon receipt of materials properly marked as Confidential, the Receiving Party shall (1) return or destroy the unmarked materials and (2) reasonably ensure that others to whom the unmarked materials were disclosed have not retained copies. In the case of inadvertently produced privileged or work product documents, Fed. R. Civ. P. 26(b)(5)(B) applies. Privileged Materials include any materials that contain information protected from disclosure as defined by the Federal Rules of Civil Procedure or the Federal Rules of Evidence.

21. This Order does not govern the use of Confidential Information at trial. The Parties and the Court (or a Magistrate Judge to whom the proceedings have been referred) determine the appropriate procedures to govern the use of Confidential Information at trial.

22. The terms of this Order remain in full force and effect after termination of this Action, unless modified, superseded, or terminated by the parties' written agreement or by this Court's order.

23. Within 30 days after completion of this litigation, counsel for the Receiving Party shall collect all Confidential Information and return it to the Designating Party, including any writing or communication reproduction, paraphrasing, or other disclosure. Attorney work product or pleadings containing information derived from Confidential Information may be destroyed rather than returned to the Designating Party. For purposes of this Order, this Action is complete upon (1) entry of a dismissal with prejudice of the entire action, (2) upon 10 days following the entry of a final, non-appealable judgment, or (3) 10 days following the exhaustion of all appeals from a final judgment.

24. If any attorney work product or pleadings containing information derived from Confidential Information is destroyed pursuant to Paragraph 18, counsel for the Receiving Party shall provide to the Designating Party a certification confirming the destruction, of the Confidential Information, which includes the originals, copies, and electronic versions. The Receiving Party shall provide confirmation to the Designating Party within 60 days after the completion of this Action, unless counsel for the Receiving Party is involved in other similar litigation that is still pending as specified in Paragraph 9.

25. After completion of this Action, all parties and persons who received Confidential Information in the course of this Action shall continue not to disclose that information.

26. The parties may not withhold responsive documents on the basis that such documents include Confidential Information. No party may refuse or delay to answer or respond to any discovery request on the basis that the response or answer would contain Confidential

Information. This Order does not waive the right of any party to object to the production of information in response to discovery.

27. If a party withholds responsive documents from production on the basis of privilege, the withholding party shall provide a Privilege Log. The withholding party shall provide the Privilege Log on a rolling basis, updated at regular and reasonable intervals. With respect to **each** responsive document withheld or redacted on the basis of privilege, the withholding party shall include the following information in the log:

- a. the date of the document;
- b. the author of the document;
- c. the recipients of the document;
- d. the specific privilege being invoked; and
- e. a description of the document necessary to establish the existence of the privilege invoked.

Information qualifying as attorney work product under federal law is exempt from the requirements of this paragraph.

28. A party may not refuse to produce an entire document on the basis that the document contains both privileged and non-privileged information. When a document or material contains both privileged and non-privileged information, the withholding party shall redact the privileged information and shall produce the redacted document.

29. If a party challenges a Privileged or Confidential Designation, and the parties are unable in good faith to agree on the designation, the challenging party may move the Court to have the producing, responding, or withholding party, as the case may be, make a witness available for a deposition limited to an inquiry concerning the Privileged or Confidential Designation of any so-designated materials.

30. A party's inadvertent production of materials subject to a claim of privilege, work product, or other statutory or Court-ordered confidentiality does not waive any of the foregoing

protections for the materials, or for any other privileged or immune materials containing the same or similar subject matter. A party may not use an inadvertent production in this Action as a basis for arguing that a claim of privilege, work product, or other statutory or Court-ordered confidentiality has been waived in any other proceeding. If any party inadvertently produces such materials, upon receipt of notice of such disclosure, the receiving party shall:

- a. promptly return or delete the materials from its litigation support or other databases;
- b. destroy its notes or other work product reflecting the contents of such materials; and
- c. confirm in writing to the producing party that all copies of the recalled materials have been returned or destroyed in accordance with this Order.

If the receiving party challenges the disclosing party's claim that the materials are privileged, protected, or otherwise subject to recall, it shall present the materials in dispute to the Court under seal for a determination.

31. This Court shall retain jurisdiction after the termination of this Action to enforce the terms of this Order and to make such amendments, modifications, deletions, and additions as the Court deems necessary and appropriate.

32. Parties and counsel are advised that an intentional failure to comply with this Protective Order may be considered contempt of court or sanctionable conduct.

IT IS SO ORDERED, this 5th day of December, 2014.

s/Mark R. Abel
UNITED STATES MAGISTRATE JUDGE

EXHIBIT A

CERTIFICATE OF ACKNOWLEDGMENT OF PROTECTIVE ORDER

I, _____, declare that:

I have been given a copy of and have read the Protective Order entered in this action. I agreed to abide by the Protective Order and not to reveal or otherwise communicate to anyone or utilize any of the information designated "Confidential" that is disclosed to me except in accordance with the terms of such Order. Specifically, but not by way of limitation, I agree to use such Confidential Information only for purposes in connection with this action, and in any other proceeding filed by one or more of the lawyers for Plaintiffs alleging birth defect injuries resulting from exposure to the product(s) at issues in this action, and not for any other purpose.

I acknowledge that any violation of this Protective Order may be punishable as contempt of court or through monetary sanctions ordered by the Court, or both, and agree to submit to the jurisdiction of the court in this action for purposes of enforcing compliance with the Protective Order.

Dated: _____

Signature: _____

Name: _____